



Patent Application
Docket No. UF-243X
Serial No. 09/648,864

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Janet L. Andres, Ph.D.
Art Unit : 1646
Applicants : Howard M. Johnson, Mustafa G. Mujtaba
Serial No. : 09/648,864
Filed : August 25, 2000
Conf. No. : 6790
For : Materials and Methods for Inhibition of IgE Production

Assistant Commissioner for Patents
Washington, D.C. 20231

Considered and S.O.S.

DECLARATION OF HOWARD M. JOHNSON, Ph.D. UNDER 37 CFR §1.132

Sir:

I, Howard M. Johnson, Ph.D., hereby declare:

THAT, a copy of my *Curriculum Vitae* is attached as Appendix A to this Declaration;

THAT, I am a co-inventor of the subject matter claimed in U.S. patent application Serial No. 09/648,864 (hereinafter the '864 application);

THAT, I have read and understood the '864 application;

THAT, I have read and understood the rejection of claims in the Office Actions mailed January 28, 2002 and October 21, 2002 in the '864 application;

AND, being thus duly qualified, do further declare:

The claims of the subject application are rejected under 35 USC §103(a) as obvious over the publications by Pene *et al.* (1988), Gruschwitz *et al.* (1993), or Kimata *et al.* (1995), and further in view of Johnson *et al.* (WO 97/39127). The Examiner asserts that the cited references teach the use of interferon alpha to downregulate IgE production. While acknowledging that the primary references do not teach that interferon tau can downregulate IgE production, the Examiner asserts that it would have been obvious to substitute interferon tau for interferon alpha in view of the Johnson *et al.* reference which, according to the Examiner, teaches that interferon

alpha and interferon tau bind to the type I receptor and have similar biological activities. From this, the Examiner concludes that the ordinarily skilled artisan, at the time of the subject invention, would have expected that interferon tau would downregulate IgE production since interferon alpha and interferon tau both bind to the type I receptor and shared some biological activities.

In my opinion, based on evidence available at the time of the subject invention, it was not obvious or predictable to a person of ordinary skill in the art that interferon tau, or chimeras of interferon tau, would function to downregulate IgE production, even in view of the teachings in the art that interferon alpha downregulates IgE. First, I note that the Examiner compares interferon tau with interferon alpha in the singular, but this is misleading. There are over 15 different functional interferon alpha genes, and they vary in specific activity (antiviral activity/unit of protein), and in relative toxicities toward cells, to mention only some of their disparate properties (Barnes *et al.*, 2002). Any differences or similarities in function between the interferon alpha species were not obvious and had to be determined empirically. Thus, even among interferon alphas, the ordinarily skilled artisan at the time of the invention was unable to predict what activity a given species of interferon alpha would exhibit beforehand.

The type I interferons, of which interferon tau and the interferon alphas are members, activate upwards of 200 different genes, but beyond those mentioned by the Examiner, there is little knowledge in the art even today of the pattern of activation by the various type I interferons (Brierley *et al.*, 2002). Among these 200 or so genes we know virtually nothing beyond the few which have already been reported for interferon tau. Therefore, I submit that one cannot predict whether interferon tau and the interferon alphas will activate the same 200 plus genes and have the same functional activity. Scientists involved in interferon research are also beginning to realize that there may be receptor subunits previously unknown for interferons, and the relationship of interferon tau to these subunits is unknown (Kotenko *et al.*, 2003).

While interferons tau and alpha activate transcription factors STAT1 and STAT2, as well as the 2'-5' synthetase system that regulates protein synthesis, research suggests that there are differences in the activation of other STAT transcription factors. For example, while it has been reported that some interferon alphas activate STAT 4, STAT5, and STAT6, there are no reports

that interferon tau activates these transcription factors even though several years have passed since the reports for interferon alphas were published (Fasler-Kan *et al.* 1998; Rogge *et al.*, 1998).

Moreover, not all interferon properties can be ascribed to activation of STAT transcription factors. Using interferon gamma as an example, interferons appear to have effects independent of STATs in the induction of cell functions (Ramana *et al.*, 2002). Further, both the interferons and some of the interferon receptor subunits undergo nuclear translocation. This suggests that the interferons and/or the receptors have direct effects on gene activation independent of STATs. This has been demonstrated for the case of epidermal growth factor receptor, which has been shown to directly activate genes in the nucleus (Lin *et al.*, 2001). The differences in amino acid sequence between interferon tau and the interferon alphas preclude the ordinarily skilled artisan from predicting that interferon tau and interferon alphas will recognize similar promoter regions for genes, and thus precludes predicting whether similar genes will be activated.

In the absence of being able to predict which genes are activated by interferon tau and the interferon alphas, the ordinarily skilled artisan, at the time of the subject invention, certainly could not have predicted with a reasonable level of confidence that interferon tau would downregulate IgE production. At best, the ordinarily skilled artisan could only speculate, given the knowledge that interferon alpha downregulated IgE production, that interferon tau would downregulate IgE. Given the evidence and information available at the time of the subject invention, the ordinarily skilled artisan would have just as likely predicted that interferon tau would not downregulate IgE production.

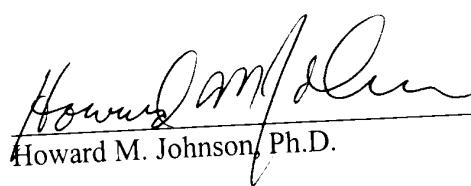
Accordingly, I respectfully submit, based on my numerous years of involvement in interferon research and on the evidence presented herein, that the invention claimed in the '864 application is not obvious over the cited references.

A copy of each publication cited herein is attached to this Declaration.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or of any patent issuing thereon.

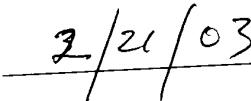
Further declarant sayeth naught.

Signed:



Howard M. Johnson, Ph.D.

Date:



2/21/03

APPENDIX A

February 2003

CURRICULUM VITAE
HOWARD M. JOHNSON

EDUCATION:

The Ohio State University, June 1962, Ph.D.
The Ohio State University, December, 1959, M.S.
The Ohio State University, June, 1958, B.S.

PROFESSIONAL EXPERIENCE:

Graduate Assistant in Immunology, The Ohio State University, 1958-1959. Research Associate in Division of Hematology, College of Medicine, The Ohio State University, 1959-1963. Research involved major histocompatibility antigens of leukocytes and platelets.

Federal Government, 1963-1975. Research involved immunochemical and immunological study of microbial toxins, interferons, haptens, and regulatory lymphocytes.

Associate Professor, Department of Microbiology, University of Texas Medical Branch, Galveston, Texas, 1975-1978.

Professor, Department of Microbiology, University of Texas Medical Branch, Galveston, Texas, 1978-1984.

Visiting Professor/Research Scientist, Department of Comparative and Experimental Pathology, University of Florida, Gainesville, Florida, 1984-1985.

Professor, Department of Comparative and Experimental Pathology, University of Florida, Gainesville, Florida, 1985 to 1988.

Graduate Research Professor, Department of Microbiology and Cell Science, University of Florida, Gainesville, Florida, 1988 to present. Research involves interferons, interleukins, neuroendocrine hormones, growth factors, receptors, structure/function of proteins, signal transduction, cell cycle events and second messengers.

University of Florida Research Foundation Professor, July 1997 to July 2000.

GRADUATE AND POSTDOCTORAL TRAINING AND ADMINISTRATION:

Advisor to fourteen Ph.D. students. Most notable achievement was discovery of feline AIDS virus by one of the students.

Advisor to three M.S. students.

Served on the committees of over 20 Ph.D. students.

Trained nine postdoctoral students.

Served on a task force for the provost at the University of Florida on evaluation of the Division of Sponsored Research and the Graduate School. Evaluation involved assessing the duties of the two units, including responsibilities and budget, and based on this, making recommendations as to whether the two units should remain separate or be combined.

HONORS:

American Men of Science

Sigma Xi

Financial Scholarship, Senior Year of Undergraduate School

EDITORIAL BOARDS AND REVIEW GROUPS:

Member, National Advisory Council of the National Institute

of Allergy and Infectious Diseases, Beginning January, 1994-1998.

Member, Research Committee of the American Heart Association (AHA) (1991-1996);

Chairman, Immunology and Microbiology Study Committee of AHA (1993-1996); Chairman

Subgroup C for AHA Established Investigators (1992-1993).

Editorial Board of Journal of Immunology

Editorial Board of Infection and Immunity

Graduate Study Panel of the National Science Foundation

Member, Neurology C Study Section, National Institutes of Health (Oct., 1987-June 1991)

Ad hoc Reviewer:

J. Leukocyte Biology, Cancer Research, Proceedings Natl. Acad. Sci. USA, Science, J. Infectious
Diseases, Quarterly Review of Biology, J. Natl. Cancer Inst., J. Biological Chemistry, Arthritis
and Rheumatism

Consultant, National Institute of Mental Health

Consultant, National Institute of Cancer

SOCIETY MEMBERSHIPS AND SPECIALTY BOARDS:

American Association of Immunologists

American Society for Microbiology

American Association for the Advancement of Science

Sigma Xi

New York Academy of Sciences

Society for Experimental Biology and Medicine

American Society for Biochemistry and Molecular Biology

SELECTIVE COMMITTEES AT THE UNIVERSITY OF FLORIDA:

1. Search Committee, Vice President for Institute for Food and Agriculture Science, 1989.
2. Search Committee, President of University of Florida, 1990.
3. Search Committee, Director of Interdisciplinary Center for Biotechnology, 1988.
4. Provost Task Force, Evaluation of Graduate School/Division of Sponsored Research.
5. Established Center for Inflammatory Host Defense and Tissue Injury; was first Director.
6. Task Force for Sponsored Research.

ENTREPRENEURSHIPS:

1. Founder and President, Superferons, Inc.
2. Holds patent on arginine vasopressin-binding antihypertensive peptide.
3. Patents pending on antitumor and antiviral properties of interferon tau.
4. Patents pending on the use of interferon tau in the treatment of autoimmune diseases such as multiple sclerosis (MS).
5. Patents pending on use of combination of IL 10 and TGF β in the treatment of MS.
6. Patents pending on superantigens in human disease.
7. Holds patent on retroviral superantigens and their uses in treatment of human diseases such as AIDS.
8. Patents pending on the functional domain of IFN γ .

SELECTIVE INVITED SEMINARS:

1980 Third International Congress of Immunology. Paris, France.
1981 First International Interferon Conference. Rotterdam, Netherlands.
1985 Joint meeting of the 17th Leucocyte Culture Conference and 22nd Meeting of RES. Ithaca, NY.
1986 Sixth International Congress of Immunology. Toronto, Canada.
1988 First International Conference of Neuroendocrinimmunology. Venice, Italy.
1989 Philippe Laudat Conference on the Neuroendocrinimmune Network:Molecular Aspects. Strasbourg, France.
1990 International Society for Neuroimmunomodulation. Florence, Italy.
1991 FASEB Summer Conference on Neuroimmunology. Vermont.
1992 International Biotechnology Expo. San Francisco, CA.
1993 Cancer Research Institute Workshop on superantigens, University of Michigan/Parke-Davis seminar on superantigens
1995 Second National Conference on Human Retroviruses and Related Infections, Washington, D.C.
1995 Third Congress of the European Society for Veterinary Virology, Interlaken, Switzerland.
1995 Ciba-Geigy, Bern, Switzerland.
1996 European Interferon Society, Hanover, Germany.

Academic and Industry:

Univ. of Texas, Austin. Baylor Coll. of Medicine, Houston, TX. Genentech, South San Francisco, CA.
Roche Institute and Hoffmann-LaRoche, Nutley, NJ. Cetus, Oakland, CA.

TRAINEES:

Postdoctoral:

C. Robbins, Ph.D.	1979-1980	"Interferon signal transduction"	Research Scientist Genentech, Inc.
R. Saneto, Ph.D.	1980-1981	"Interferon signals"	Research Associate OR Primate Center
C. Pontzer, Ph.D.	1988-1994	"Biological response modifiers"	Assistant Professor Univ. of Maryland
M. Downs, D.V.M.	1989-1991	"Neuroimmune receptors"	Assistant Professor Univ. of Georgia
N. Griggs, Ph.D.	1990-1992	"Superantigens"	Postdoctoral Associate Univ. of Virginia
P.E. Cruz	1996-1997	"Induction of apoptosis by interferons"	Postdoctoral Associate Univ. of Florida
P.S. Subramaniam	1992-Date	"Signal transduction by tau interferon"	Asst. Research Scientist Microbiol. & Cell Sci. Univ. of Florida
T. Tanabe	1993-1998	"V β -specific T cell	Postdoctoral Associate

		expansions by HIV Nef"	Univ. of Florida
B. Torres	1996-2001	"Viral and bacterial superantigens"	Asst. Research Scientist Univ. of Florida
M.M. Green	1996-2000	"IFN γ receptor studies"	Private Laboratory Gainesville, FL
A.C. Hobeika	1998-1999	"Cell cycle effects of type I IFNs"	Postdoctoral Associate Duke University

Predoctoral:

L.C. Osborne	1980-1987	"Gamma interferon" Bethesda, MD	Food & Drug Admin.
S.R. Evans	1980-1981	"Biological response modifiers"	Private Laboratory Houston, TX
J.K. Yamamoto	1980-1981	"Natural killer cells"	Associate Professor Univ. Of Florida
B.A. Torres	1980-1981 1993-1995	"Interleukins and "Viral superantigens"	Bio-Rad Labs Research Scientist Univ. of Florida
N. Abdullah	1989-1990	"Non-hemopoietic growth factors"	Postdoctoral Associate N.I.H.
H. Magazine	1987-1990	"Gamma interferon structure"	Professor and Chair Queens College, NY
M. Jarpe	1987-1990	"Structure/function of gamma interferon"	Research Scientist Cambridge Neurosciences
J. Soos	1991-1994	"Toxic shock toxin superantigen"	Research Associate SmithKline Beecham
B. Szente	1992-1995	"Structure/function of IFN γ transcriptionfactors"	Research Associate SmithKline Beecham
M. Van Volkenburg	1992-1993	"Structure/function of IFN γ receptor"	Pfizer Pharmaceuticals Groton, CT
A.C. Hobeika	1993-1997	"Molecular effects of IFN tau on prostate cancer"	Postdoctoral Associate Duke University

G.Q. Perrin	1994-1999	"Structural basis for IL10 function"	Postdoctoral Associate University of Florida
M.G. Mujtaba	1995-1999	"Interferon tau modulation of immunity"	Postdoctoral Associate Harvard University
K. E. Comatas	1997-1999	"Intracellular domain of IFN γ receptor"	Research Associate Duke University
J. Larkin	1996-2000	"Nuclear translocation of IFN γ /receptor complex and signal transduction"	Postdoctoral Associate University of Pennsylvania
S. Kominsky	1996-2000	"Intracellular signalling by IFN γ "	Postdoctoral Associate Johns Hopkins University
A. Anderson	2001-Present	"Superantigen T cell regulation"	
M. Burkhart	2001-Present	"Interferon signal transduction"	
L. Flowers	2002-Present	"JAK2 inhibitors"	

PUBLICATIONS:

1. Wilson HE, Johnson HM, Dodd MC. 1961 The serological detection of leukocyte and platelet antibodies. *Blood: J Hematol* 17:363.
2. Wilson HE, Johnson HM, Dodd MC. 1963 The antigenic specificity of human leukocytes. *Proceedings of the IX Congress of International Society of Hematology* 2:553-559.
3. Johnson HM, Dodd MC. 1964 Specific inhibition of anti-D by human urinary mucoprotein. *Nature* 203:1082.
4. Johnson HM. 1964 Human blood group A₁ specific agglutinin of the butter clam *Saxidomus giganteus*. *Science* 146:548-549.
5. Johnson HM, Frey PA, Angelotti R, Campbell JE, Lewis KH. 1964 Haptenic properties of paralytic shellfish poison conjugated to proteins by formaldehyde treatment. *Proc Soc Exp Biol Med* 117:425-430.
6. Wilson HE, Johnson HM, Dodd MC. 1965 Histocompatibility testing. *Publ. No. 1229. Natl Acad Sci Natl Res Council.*
7. Johnson HM, Brenner K, Angelotti R, Hall HE. 1966 Serological studies of types A, B, and E botulinal toxins by passive hemagglutination and bentonite flocculation. *J Bacteriol* 96:967-974.

8. Johnson HM, Mulberry G. 1966 Paralytic shellfish poison: Serological assay by passive hemagglutination and bentonite flocculations. *Nature* 211:747-748.
9. Johnson HM, Brenner K, Hall HE. 1966 The use of water soluble carbodiimide as a coupling reagent in the passive hemagglutination test. *J Immunol* 97:791-796.
10. Johnson HM, Hall HE, Simon M. 1967 Enterotoxin B: Serological assay in cultures by passive hemagglutination. *Appl Microbiol* 15:81-818.
11. Johnson, HM, Smith B, Hall HE, Lewis KH. 1967 Serological specificity of types A and B botulinal toxins and antitoxins. *Proc Soc Exp Biol Med* 126:856-861.
12. Johnson HM, Smith BG, Hall HE. 1968 Quantitative passive hemagglutination: A study of some of the variables of the coupling reaction. *Int Arch Allergy* 33:511-520.
13. Johnson HM, Peeler JT, Hall HE. 1968 Quantitative passive hemagglutination: Adaptation of the cell migration technique to measurement of antibodies to *E. coli*. *J Immunol* 101:868-875.
14. Johnson HM, Smith BG, Brenner K, Hall HE, Lewis KH. 1968 Serological specificity of botulinal toxins. Proceedings from Program of U.S.-Japan Cooperation for the Development of Natural Resources, Honolulu, Hawaii, Oct. 7-10, 1968.
15. Wilson HE, Johnson HM, Dodd MC. 1968 Induction of isoantibodies to human leukocytes. *Transplantation* 6:374-381.
16. Johnson HM, Brenner K, Hall HE. 1969 Immunochemistry of formamide-extracted antigen from Clostridium perfringens cell walls. *J Bacteriol* 100:176-179.
17. Johnson HM, Peeler JT. 1970 Quantitative passive hemagglutination: Adaptation of cell migration techniques to measurement of antibodies to protein. *J Immunol* 104:1079-1086.
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19. Johnson HM, Smith BG, Lewis KH. 1971 Serological specificity of type E botulinal toxin. *Proc Soc Exp Biol Med* 137:973.
20. Johnson HM, Bukovic JA, Kauffman PE, Peeler JT. 1971 Staphylococcal enterotoxin B: Solid-phase radioimmunoassay. *Appl Microbiol* 22:837.
21. Johnson HM, Smith BG. (1972). Haptenic relationship of p-azobenzenesulfonate and some structurally related food dyes. *Immunochem* 9:253.
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35. Johnson HM, Bukovic JA, Baron S. (1975). Interferon inhibition of the primary in vitro antibody response to a thymus-independent antigen. *Cell Immunol* 20:104-109.
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48. Johnson HM. (1977). Effect of interferon on antibody formation. Texas Reports 35:357-369.
49. Johnson HM, Baron S. (1977). Effect of low levels of cyclic ribonucleotides on mitogen and virus induced production of interferon. Proceedings of W. Alton Jones Cell Science Center Symposium. Advances Exp Biol Med 10:25-35.
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52. Johnson HM. (1978). Differentiation of the immunosuppressive and antiviral effects of interferon. Cell Immunol 36:220-230.
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55. Langford MP, Stanton GJ, Johnson HM. (1978). Biological effects of SEA on human peripheral lymphocytes. Infect Immun 22:62-68.
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62. Georgiades JA, Langford MP, Stanton GJ, Johnson, HM. (1979). Purification and potentiation of human immune interferon. IRCS Medical Science 7:559.
63. Goldstein LD, Georgiades JA, Langford MP, and Johnson HM. (1979). Human immune interferon: Isoelectrofocusing analysis. IRCS Medical Science 7:560.
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65. Fleischmann WR, Georgiades JA, Osborne LC, H.M. Johnson HM (1979). Potentiation of interferon activity by mixed preparations of fibroblast and immune interferon. Infect Immun 26:248-253.
66. Fleischmann WR, Georgiades JA, Osborne LC, Dianzani F, Johnson HM. (1979). Induction of an inhibitor of interferon action in a mouse lymphokine preparation. Infect Immun 26:949-955.
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68. Johnson HM, Langford MP, Stanton GJ. (1980). Suppression of the immune response by staphylococcal enterotoxins. From FDA Symposium "Inadvertent Modification of the Immune Response." Asher, IM (ed), US Government Printing Office, p 115-122.

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72. Archer DL, Smith BG, Johnson HM. (1980). Effects of toxicants on T-cell subpopulations as determined by lymphokine activity. *Archives of Toxicology, Suppl. No. 4, Beitrag* 29:138-142.

73. Georgiades JA, Langford MP, Goldstein LD, Blalock JE, Johnson HM. (1980). Human immune interferon: Purification and activity against a transformed cell line. In: Interferon: Properties and Clinical Uses (Khan A, Hill NO, Dorn GL, eds) Leland Fikes Foundation Press, p 97-110.

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75. Johnson HM, Blalock JE. (1980). Interferon-induced suppressor factor: Possible mechanism of regulation of normal and tumor cells. In: Interferon: Properties and Clinical Uses Khan A, Hill NO, Dorn GL, eds). Leland Fikes Foundation Press, p 509-519.

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81. Saneto R, Holstun S, Johnson HM. (1980). Interferon blocks endotoxin activation of the hexose monophosphate shunt pathway. *IRCS Medical Sciences* 8:920-922.

82. Johnson HM. (1980). Similarities in the suppression of the immune response by interferon and by a thiol-oxidizing agent. *Proc Soc Exp Biol Med* 164:380-385.

83. Archer DL, Smith BG, Johnson HM. (1980). Direct and induced suppression of in vitro antibody production by selected phenols: A comparison to virus-type interferon. In: Biological Relevance of Immune Suppression as Induced by Genetic, Therapeutic, and Environmental Factors (Dean JH, ed), Van Nostrand Reinhold.

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85. Archer DL, Wess JA, Johnson HM. (1981). Inverse relationship between immune interferon induction and mitogen effects on the maturation of the primary antibody response. *Immunopharmacology* 3:71-81.

86. Johnson HM. (1981). Cellular regulation of immune interferon production. *Antiviral Research* 1:37-46.

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SUPPORT

NIH R37 AI25904 Superantigens: Characterization and Role in Disease

NIAID, NIH 03/01/93 - 02/28/03

H.M. Johnson, PI 20% effort Approximately \$1,800,000 TDC

The major goal of this project is to better characterize superantigens such as the staphylococcal enterotoxins, with respect to receptors, signal transduction, and role in induction and exacerbation of autoimmune diseases such as experimental allergic encephalomyelitis (EAE) and to determine the role of superantigens as virulence factors in disease.

NIH CA69959 Structure/Function Studies of Interferon Tau

NCI, NIH 12/01/99 - 12/31/03

H.M. Johnson, PI 10% effort \$570,999 TDC.

The major goal of this project is to establish the unique properties of a novel interferon, interferon tau (IFN τ), with respect to its antiviral and antiproliferative activities, as well as its lack of toxicity as compared to other type I IFNs.